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(54) **RENAL NERVE ABLATION USING CONDUCTIVE FLUID JET AND RF ENERGY**

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(58) **Field of Classification Search**

None

See application file for complete search history.

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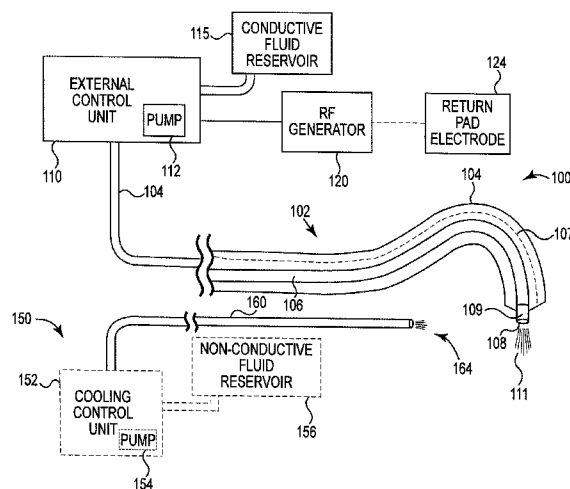
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(57)

ABSTRACT

An ablation catheter is dimensioned for advancement through a vessel of the body. The catheter includes a lumen configured to receive a pressurized electrically conductive fluid. A nozzle is fluidly coupled to the distal end of the pressurizable lumen and configured to direct a jet of the pressurized conductive fluid at a wall of a target vessel, such as a renal artery, to create or expand a hole through the target vessel and to fill the hole and at least some of the space adjacent to the hole with the conductive fluid. An electrical conductor extends at least partially along the catheter and terminates proximate or at the distal end of the pressurizable lumen. The electrical conductor is configured to conduct radiofrequency energy to the conductive fluid sufficient to ablate target tissue, such as perivascular renal nerve tissue, proximate the hole.

19 Claims, 8 Drawing Sheets



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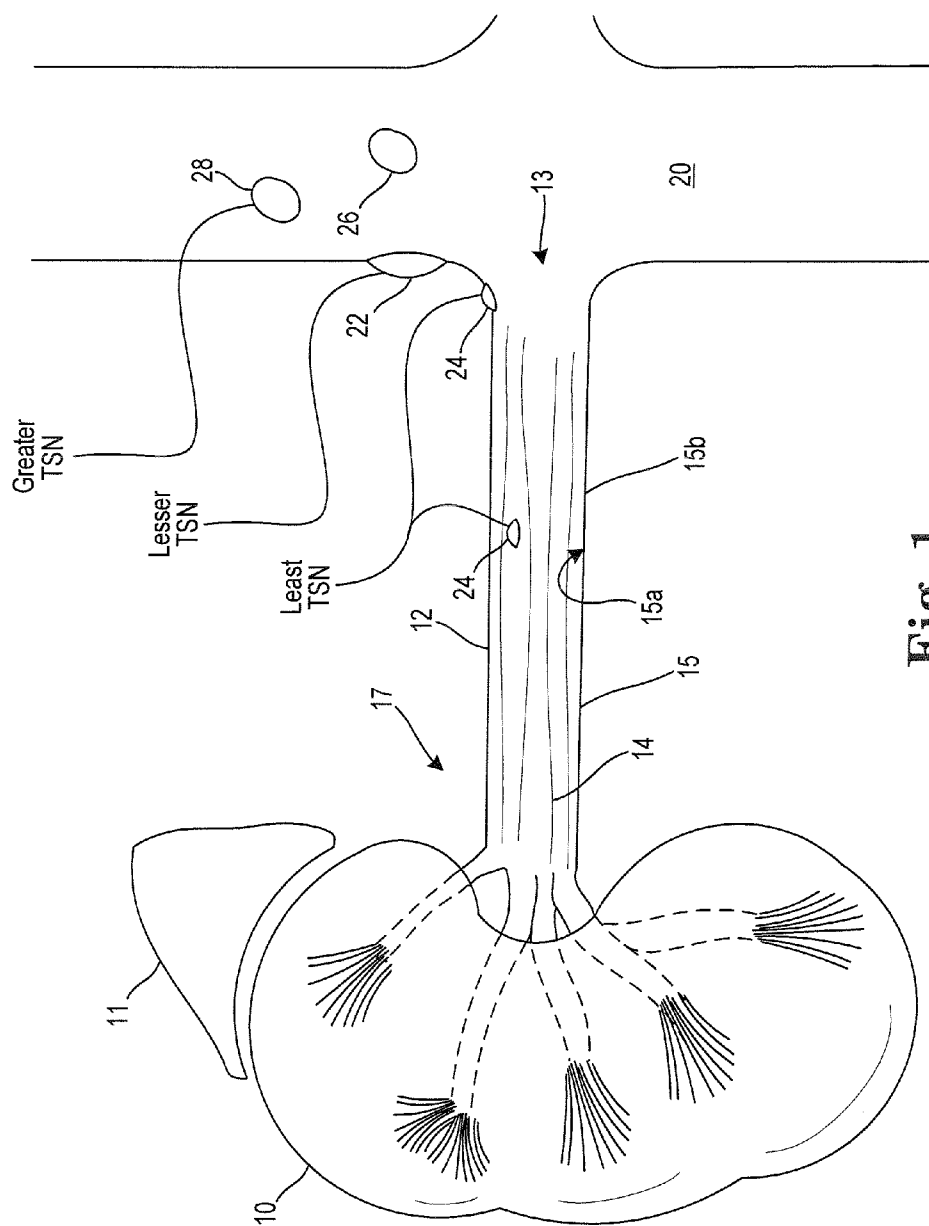
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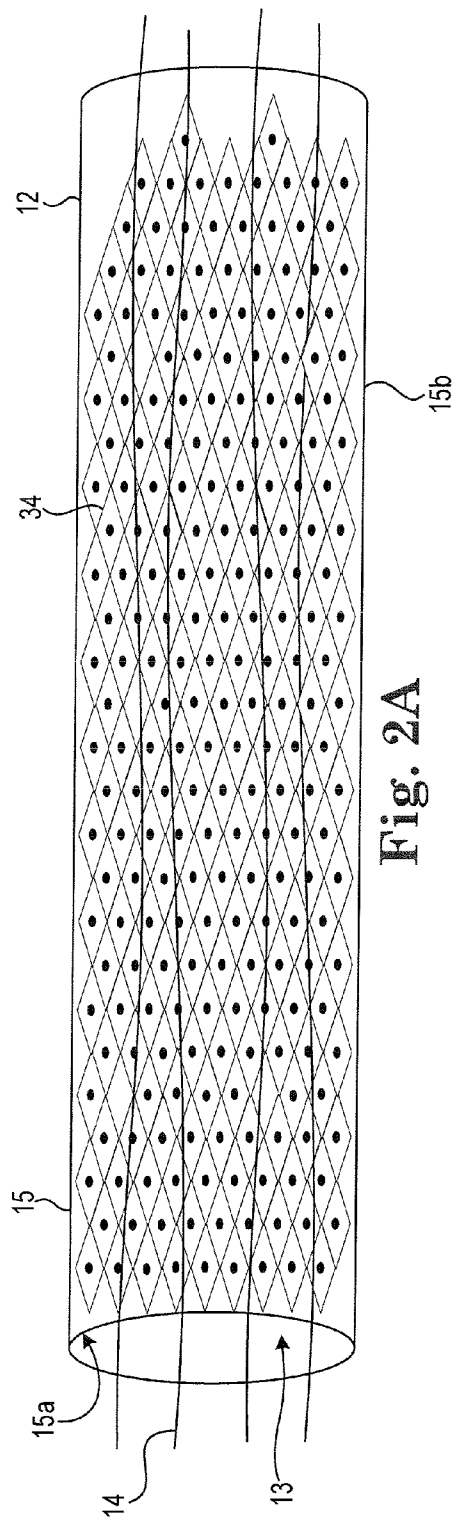


Fig. 2A

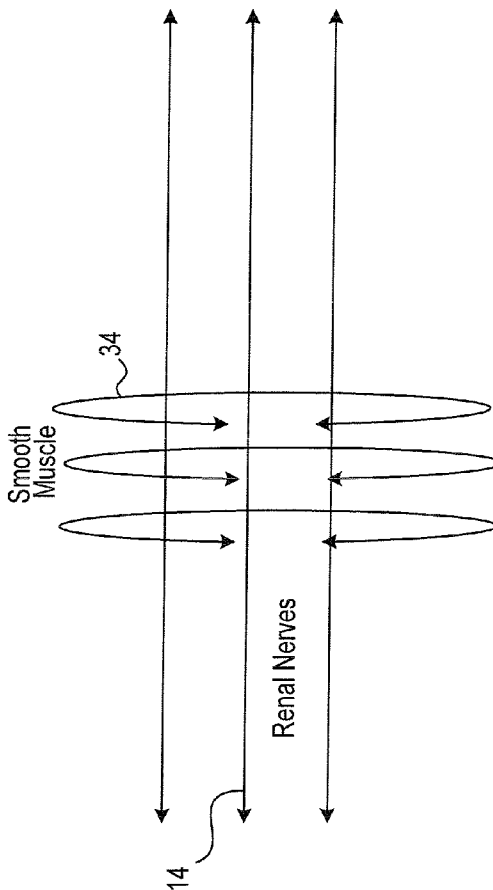


Fig. 2B

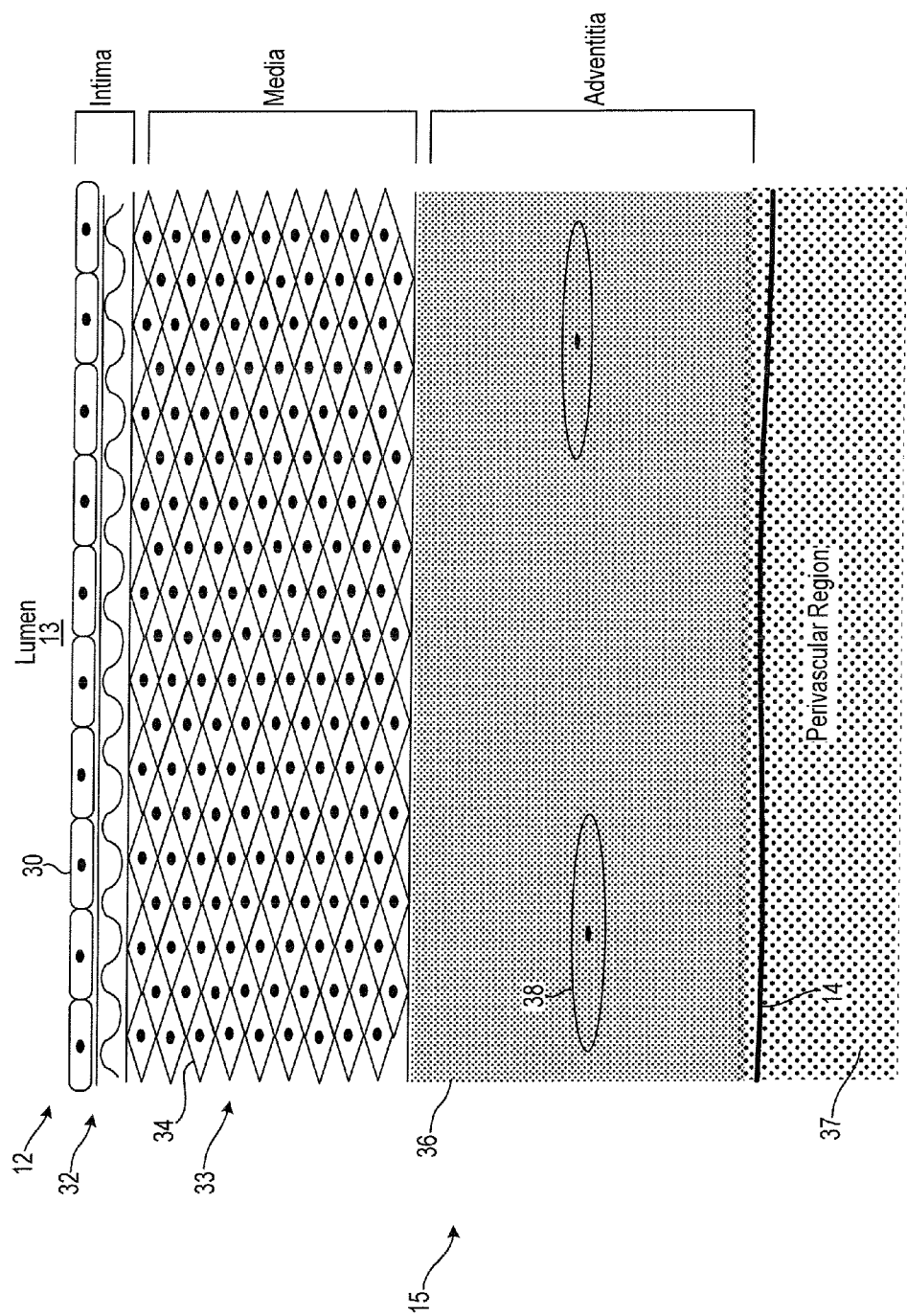


Fig. 3A

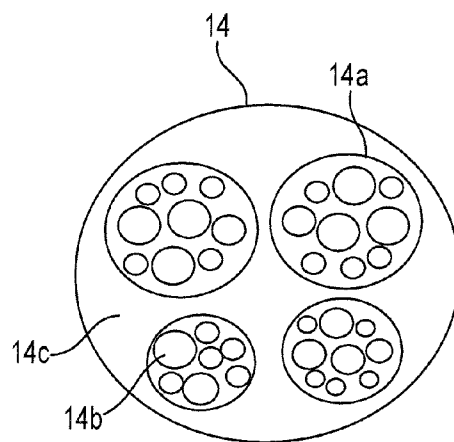
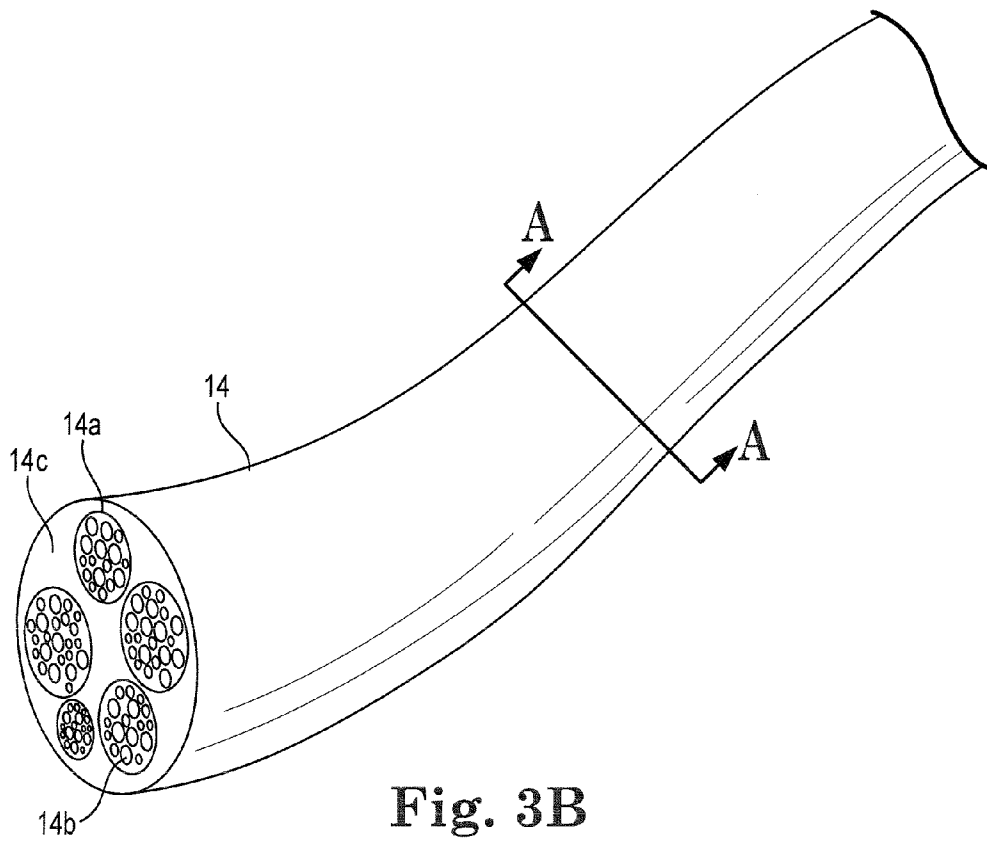


Fig. 3C

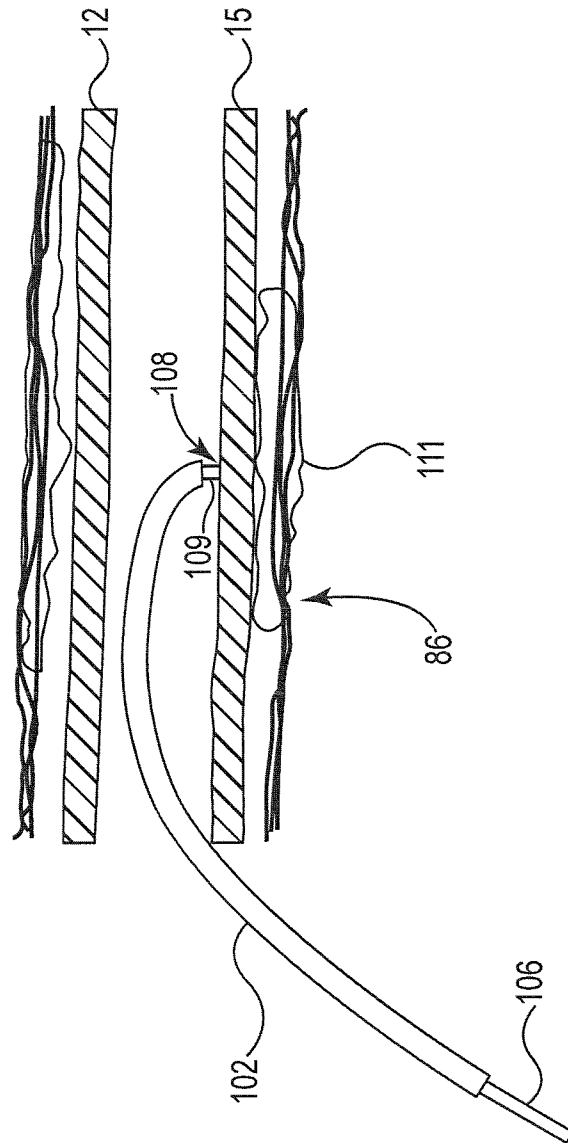


Fig. 4

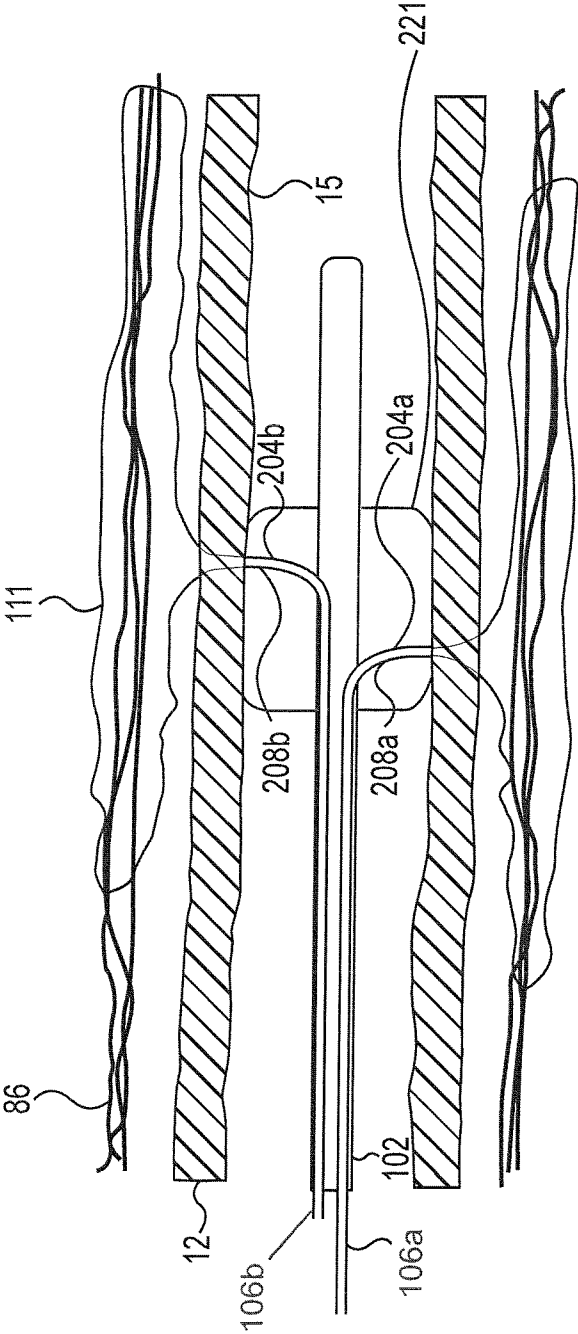
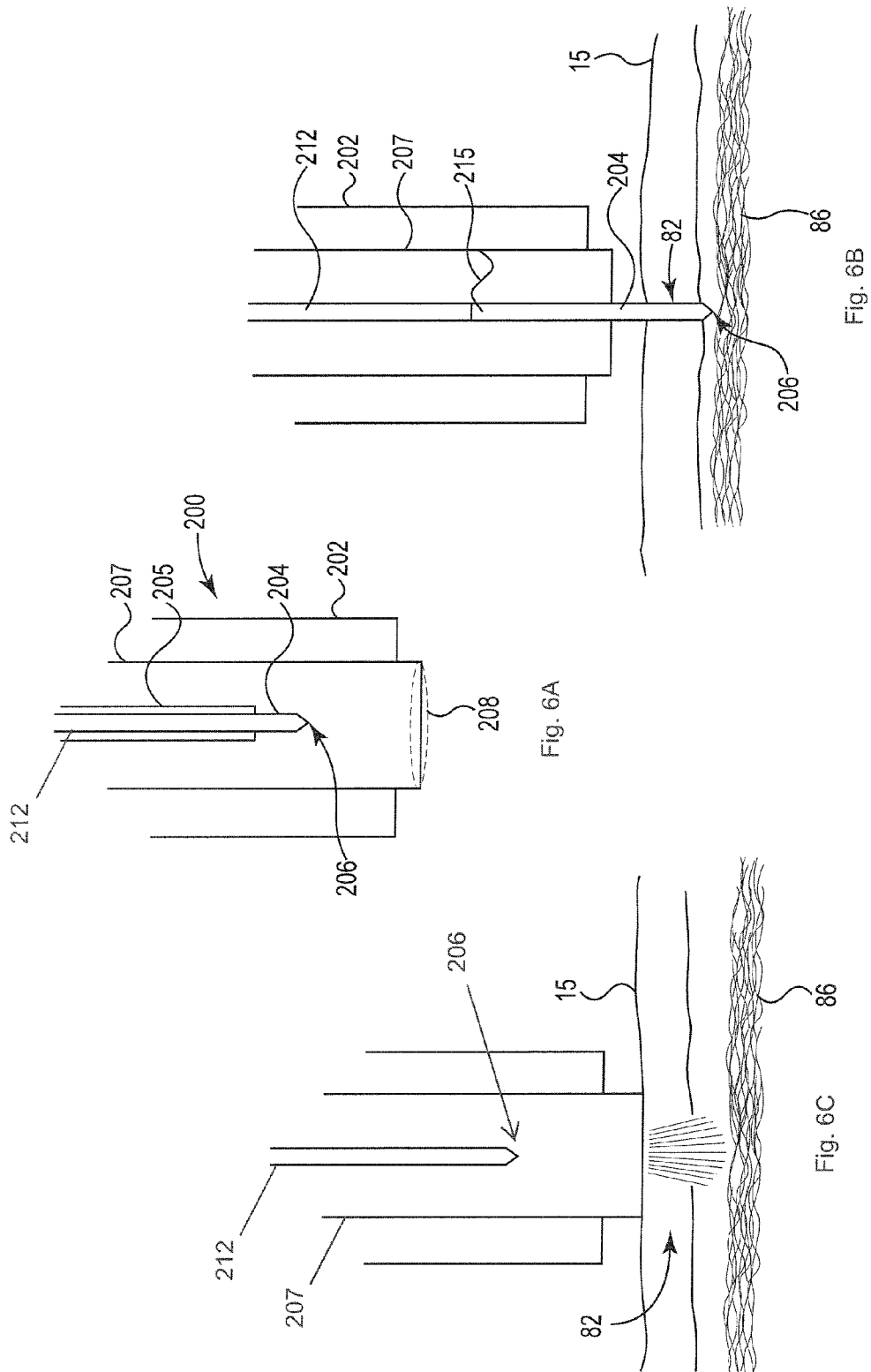


Fig. 5



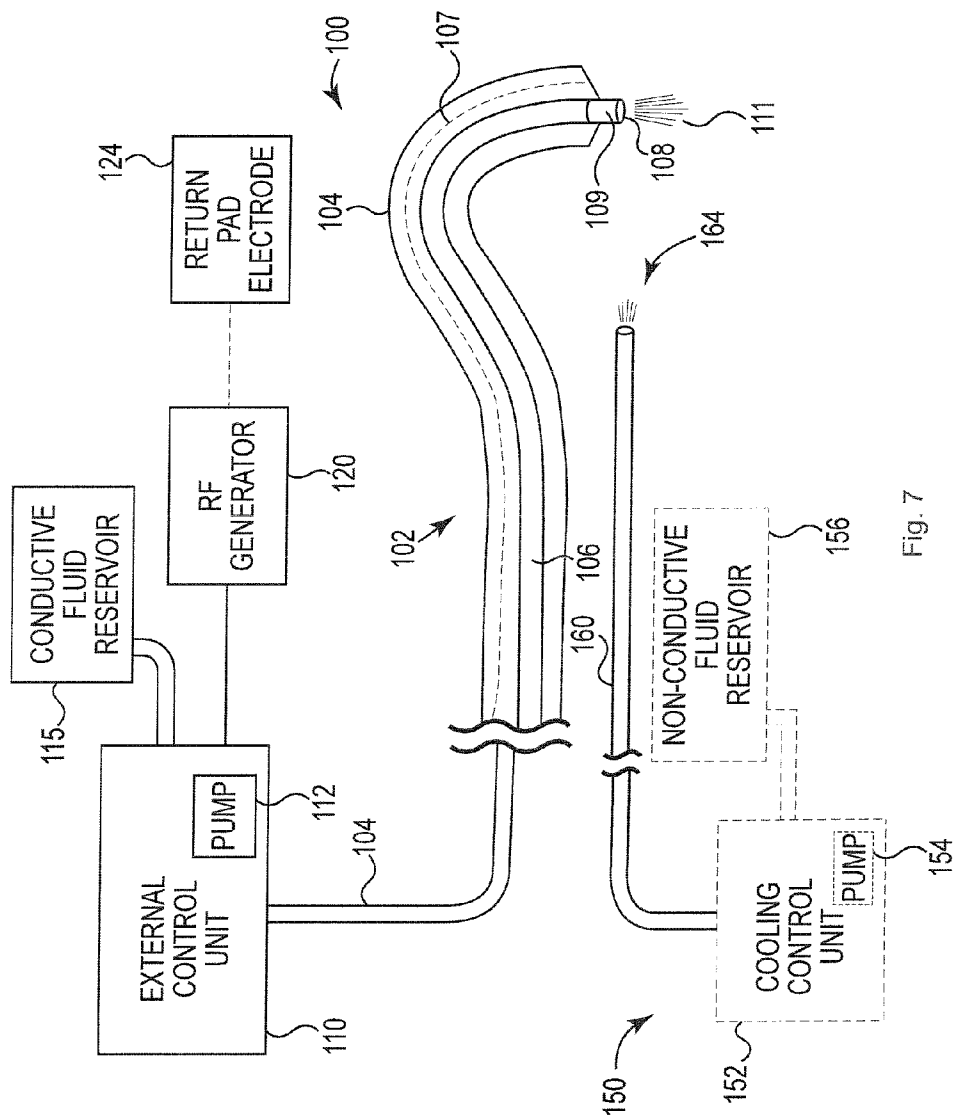


Fig. 7

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RENAL NERVE ABLATION USING CONDUCTIVE FLUID JET AND RF ENERGY

RELATED PATENT DOCUMENTS

This application claims the benefit of Provisional Patent Application Ser. No. 61/406,304 filed Oct. 25, 2010, to which priority is claimed pursuant to 35 U.S.C. §119(e) and which are hereby incorporated herein by reference.

SUMMARY

Embodiments of the disclosure are directed to a catheter dimensioned for advancement through a vessel of the body. A pressurizable lumen of the catheter is configured to receive a pressurized electrically conductive fluid. A nozzle is fluidly coupled to a distal end of the pressurizable lumen and configured to direct a jet of the pressurized conductive fluid at a wall of a target vessel to create or expand a hole through the target vessel and to fill at least some of the space adjacent to the hole with the conductive fluid. At least one electrical conductor extends at least partially along the catheter and terminates proximate or at the distal end of the pressurizable lumen. The electrical conductor is configured to conduct radiofrequency energy to the conductive fluid sufficient to ablate target tissue in contact with the conductive fluid.

In accordance with some embodiments, a catheter includes a flexible shaft having a proximal end, a distal end, a length, and a lumen arrangement extending between the proximal and distal ends. The length of the shaft is sufficient to access a patient's renal artery relative to a percutaneous access location. A pressurizable lumen of the lumen arrangement is configured to receive a pressurized conductive fluid. A nozzle is fluidly coupled to a distal end of the pressurizable lumen. The nozzle is configured to direct a jet of the pressurized conductive fluid at a wall of the renal artery to create or expand a hole through the artery wall and to fill at least some of perivascular space adjacent to the hole with the conductive fluid. At least one electrical conductor extends at least partially along the shaft and terminates proximate or at the distal end of the pressurizable lumen. The electrical conductor is configured to conduct radiofrequency energy to the conductive fluid sufficient to ablate perivascular renal nerves in contact with the conductive fluid.

According to further embodiments, a method involves advancing a catheter through a vessel of the body to a target location proximate target tissue adjacent an outer wall of the vessel. The method further involves creating a hole through the vessel at the target location, filing the hole and at least some of the space adjacent to the hole with conductive fluid via a lumen of the catheter, and conducting radiofrequency energy along the catheter and to the conductive fluid filing the hole and the at least some of the space adjacent to the hole sufficient to ablate the target tissue. According to some embodiments, the hole is created in a wall of a renal artery, and the target tissue comprises perivascular renal nerve tissue.

These and other features can be understood in view of the following detailed discussion and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a right kidney and renal vasculature including a renal artery branching laterally from the abdominal aorta;

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FIGS. 2A and 2B illustrate sympathetic innervation of the renal artery;

FIG. 3A illustrates various tissue layers of the wall of the renal artery;

FIGS. 3B and 3C illustrate a portion of a renal nerve;

FIG. 4 illustrates a treatment catheter comprising a jet and electrode arrangement configured to deliver a pressurized, electrically conductive fluid spray through a wall of a target vessel and ablate target tissue adjacent the target vessel wall in accordance with various embodiments;

FIG. 5 illustrates a treatment catheter comprising a multiplicity of jet and electrode arrangements each configured to deliver a pressurized, electrically conductive fluid spray through a wall of a target vessel and ablate target tissue adjacent the target vessel wall in accordance with various embodiments;

FIGS. 6A-6C illustrate treatment catheters comprising a jet and electrode arrangement configured to deliver a pressurized, electrically conductive fluid spray through a wall of a target vessel and ablate target tissue adjacent the target vessel wall in accordance with various embodiments; and

FIG. 7 shows a representative RF renal therapy apparatus in accordance with various embodiments of the disclosure.

DESCRIPTION

Embodiments of the disclosure are directed to apparatuses and methods for ablating extravascular target tissue from within a vessel. Embodiments of the disclosure are directed to apparatuses and methods for ablating perivascular renal nerves from within the renal artery or other nearby vessel for the treatment of hypertension. Embodiments of the disclosure are directed to an intravascular catheter having a high-pressure fluid jet arrangement for creating a small hole through a vessel wall, dispensing an electrically conductive fluid through the hole and into perivascular space adjacent the vessel wall, and delivering RF energy to the conductive fluid and surrounding tissue of sufficient power to ablate perivascular tissue, such as perivascular renal nerve tissue, in contact with the conductive fluid.

When using RF electrode(s) placed in the renal artery for ablation of perivascular renal nerves for treatment of hypertension, the highest current density and thus the greatest heating is typically adjacent to the electrode. All the current that reaches the target tissue must also pass through the renal artery wall. In order to achieve tissue temperatures for effective ablation of the renal nerves, the renal artery can also be injured. Active cooling can be provided, but requires a larger catheter and a more complex system. Improved approaches to reducing injury to the renal artery during ablation of the renal nerves are disclosed herein.

Embodiments described in the present disclosure provide for sufficient ablation of target nerves while reducing injury to the renal artery by using a high-velocity jet of highly conductive fluid to cut a very small hole in the artery wall and conduct the current past the artery wall. In some configurations, an external control unit pressurizes a conductive fluid (such as saline with conductive additives) and also powers the RF transmission. A catheter with a pressurized fluid lumen and a conductor attaches to the external control unit.

In accordance with various method embodiments, a catheter is guided to the treatment location and directed against the wall of a patient's renal artery. A conductive fluid is pressurized and transported through a pressurizable fluid lumen of the catheter and exits through a nozzle. A brief activation of the conductive fluid jet is used to create a hole through the artery wall and fill the hole with the conductive

fluid. Depending on the duration of jet activation, a volume of conductive fluid will also dissect and collect in the perivascular space.

Radiofrequency (RF) energy or other form of high-frequency AC energy is passed along an electrical conductor that extends between the distal and proximal ends of the catheter. The electrical conductor may take the form of a metallic tube which also serves as the conductive fluid lumen of the catheter. The RF energy passes preferentially through the conductive fluid, through the small hole in the artery wall, and to the perivascular tissue, where it spreads and heats the perivascular renal nerve tissue due to the higher impedance of the perivascular renal nerve tissue relative to that of the conductive fluid.

Various embodiments of the disclosure are directed to apparatuses and methods for renal denervation for treating hypertension. Hypertension is a chronic medical condition in which the blood pressure is elevated. Persistent hypertension is a significant risk factor associated with a variety of adverse medical conditions, including heart attacks, heart failure, arterial aneurysms, and strokes. Persistent hypertension is a leading cause of chronic renal failure. Hyperactivity of the sympathetic nervous system serving the kidneys is associated with hypertension and its progression. Deactivation of nerves in the kidneys via renal denervation can reduce blood pressure, and may be a viable treatment option for many patients with hypertension who do not respond to conventional drugs.

The kidneys are instrumental in a number of body processes, including blood filtration, regulation of fluid balance, blood pressure control, electrolyte balance, and hormone production. One primary function of the kidneys is to remove toxins, mineral salts, and water from the blood to form urine. The kidneys receive about 20-25% of cardiac output through the renal arteries that branch left and right from the abdominal aorta, entering each kidney at the concave surface of the kidneys, the renal hilum.

Blood flows into the kidneys through the renal artery and the afferent arteriole, entering the filtration portion of the kidney, the renal corpuscle. The renal corpuscle is composed of the glomerulus, a thicket of capillaries, surrounded by a fluid-filled, cup-like sac called Bowman's capsule. Solutes in the blood are filtered through the very thin capillary walls of the glomerulus due to the pressure gradient that exists between the blood in the capillaries and the fluid in the Bowman's capsule. The pressure gradient is controlled by the contraction or dilation of the arterioles. After filtration occurs, the filtered blood moves through the efferent arteriole and the peritubular capillaries, converging in the interlobular veins, and finally exiting the kidney through the renal vein.

Particles and fluid filtered from the blood move from the Bowman's capsule through a number of tubules to a collecting duct. Urine is formed in the collecting duct and then exits through the ureter and bladder. The tubules are surrounded by the peritubular capillaries (containing the filtered blood). As the filtrate moves through the tubules and toward the collecting duct, nutrients, water, and electrolytes, such as sodium and chloride, are reabsorbed into the blood.

The kidneys are innervated by the renal plexus which emanates primarily from the aorticorenal ganglion. Renal ganglia are formed by the nerves of the renal plexus as the nerves follow along the course of the renal artery and into the kidney. The renal nerves are part of the autonomic nervous system which includes sympathetic and parasympathetic components. The sympathetic nervous system is known to be the system that provides the bodies "fight or flight" response, whereas the parasympathetic nervous system provides the "rest and digest" response. Stimulation of sympathetic nerve

activity triggers the sympathetic response which causes the kidneys to increase production of hormones that increase vasoconstriction and fluid retention. This process is referred to as the renin-angiotensin-aldosterone-system (RAAS) response to increased renal sympathetic nerve activity.

In response to a reduction in blood volume, the kidneys secrete renin, which stimulates the production of angiotensin. Angiotensin causes blood vessels to constrict, resulting in increased blood pressure, and also stimulates the secretion of the hormone aldosterone from the adrenal cortex. Aldosterone causes the tubules of the kidneys to increase the reabsorption of sodium and water, which increases the volume of fluid in the body and blood pressure.

Congestive heart failure (CHF) is a condition that has been linked to kidney function. CHF occurs when the heart is unable to pump blood effectively throughout the body. When blood flow drops, renal function degrades because of insufficient perfusion of the blood within the renal corpuscles. The decreased blood flow to the kidneys triggers an increase in sympathetic nervous system activity (i.e., the RAAS becomes too active) that causes the kidneys to secrete hormones that increase fluid retention and vasoconstriction. Fluid retention and vasoconstriction in turn increases the peripheral resistance of the circulatory system, placing an even greater load on the heart, which diminishes blood flow further. If the deterioration in cardiac and renal functioning continues, eventually the body becomes overwhelmed, and an episode of heart failure decompensation occurs, often leading to hospitalization of the patient.

FIG. 1 is an illustration of a right kidney 10 and renal vasculature including a renal artery 12 branching laterally from the abdominal aorta 20. In FIG. 1, only the right kidney 10 is shown for purposes of simplicity of explanation, but reference will be made herein to both right and left kidneys and associated renal vasculature and nervous system structures, all of which are contemplated within the context of embodiments of the disclosure. The renal artery 12 is purposefully shown to be disproportionately larger than the right kidney 10 and abdominal aorta 20 in order to facilitate discussion of various features and embodiments of the present disclosure.

The right and left kidneys are supplied with blood from the right and left renal arteries that branch from respective right and left lateral surfaces of the abdominal aorta 20. Each of the right and left renal arteries is directed across the crus of the diaphragm, so as to form nearly a right angle with the abdominal aorta 20. The right and left renal arteries extend generally from the abdominal aorta 20 to respective renal sinuses proximate the hilum 17 of the kidneys, and branch into segmental arteries and then interlobular arteries within the kidney 10. The interlobular arteries radiate outward, penetrating the renal capsule and extending through the renal columns between the renal pyramids. Typically, the kidneys receive about 20% of total cardiac output which, for normal persons, represents about 1200 mL of blood flow through the kidneys per minute.

The primary function of the kidneys is to maintain water and electrolyte balance for the body by controlling the production and concentration of urine. In producing urine, the kidneys excrete wastes such as urea and ammonium. The kidneys also control reabsorption of glucose and amino acids, and are important in the production of hormones including vitamin D, renin and erythropoietin.

An important secondary function of the kidneys is to control metabolic homeostasis of the body. Controlling homeostatic functions include regulating electrolytes, acid-base balance, and blood pressure. For example, the kidneys are

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responsible for regulating blood volume and pressure by adjusting volume of water lost in the urine and releasing erythropoietin and renin, for example. The kidneys also regulate plasma ion concentrations (e.g., sodium, potassium, chloride ions, and calcium ion levels) by controlling the quantities lost in the urine and the synthesis of calcitrol. Other hemostatic functions controlled by the kidneys include stabilizing blood pH by controlling loss of hydrogen and bicarbonate ions in the urine, conserving valuable nutrients by preventing their excretion, and assisting the liver with detoxification.

Also shown in FIG. 1 is the right suprarenal gland 11, commonly referred to as the right adrenal gland. The suprarenal gland 11 is a star-shaped endocrine gland that rests on top of the kidney 10. The primary function of the suprarenal glands (left and right) is to regulate the stress response of the body through the synthesis of corticosteroids and catecholamines, including cortisol and adrenaline (epinephrine), respectively. Encompassing the kidneys 10, suprarenal glands 11, renal vessels 12, and adjacent perirenal fat is the renal fascia, e.g., Gerota's fascia, (not shown), which is a fascial pouch derived from extraperitoneal connective tissue.

The autonomic nervous system of the body controls involuntary actions of the smooth muscles in blood vessels, the digestive system, heart, and glands. The autonomic nervous system is divided into the sympathetic nervous system and the parasympathetic nervous system. In general terms, the parasympathetic nervous system prepares the body for rest by lowering heart rate, lowering blood pressure, and stimulating digestion. The sympathetic nervous system effectuates the body's fight-or-flight response by increasing heart rate, increasing blood pressure, and increasing metabolism.

In the autonomic nervous system, fibers originating from the central nervous system and extending to the various ganglia are referred to as preganglionic fibers, while those extending from the ganglia to the effector organ are referred to as postganglionic fibers. Activation of the sympathetic nervous system is effected through the release of adrenaline (epinephrine) and to a lesser extent norepinephrine from the suprarenal glands 11. This release of adrenaline is triggered by the neurotransmitter acetylcholine released from preganglionic sympathetic nerves.

The kidneys and ureters (not shown) are innervated by the renal nerves 14. FIGS. 1 and 2A-2B illustrate sympathetic innervation of the renal vasculature, primarily innervation of the renal artery 12. The primary functions of sympathetic innervation of the renal vasculature include regulation of renal blood flow and pressure, stimulation of renin release, and direct stimulation of water and sodium ion reabsorption.

Most of the nerves innervating the renal vasculature are sympathetic postganglionic fibers arising from the superior mesenteric ganglion 26. The renal nerves 14 extend generally axially along the renal arteries 12, enter the kidneys 10 at the hilum 17, follow the branches of the renal arteries 12 within the kidney 10, and extend to individual nephrons. Other renal ganglia, such as the renal ganglia 24, superior mesenteric ganglion 26, the left and right aorticorenal ganglia 22, and celiac ganglia 28 also innervate the renal vasculature. The celiac ganglion 28 is joined by the greater thoracic splanchnic nerve (greater TSN). The aorticorenal ganglia 26 is joined by the lesser thoracic splanchnic nerve (lesser TSN) and innervates the greater part of the renal plexus.

Sympathetic signals to the kidney 10 are communicated via innervated renal vasculature that originates primarily at spinal segments T10-T12 and L1. Parasympathetic signals originate primarily at spinal segments S2-S4 and from the medulla oblongata of the lower brain. Sympathetic nerve

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traffic travels through the sympathetic trunk ganglia, where some may synapse, while others synapse at the aorticorenal ganglion 22 (via the lesser thoracic splanchnic nerve, i.e., lesser TSN) and the renal ganglion 24 (via the least thoracic splanchnic nerve, i.e., least TSN). The postsynaptic sympathetic signals then travel along nerves 14 of the renal artery 12 to the kidney 10. Presynaptic parasympathetic signals travel to sites near the kidney 10 before they synapse on or near the kidney 10.

With particular reference to FIG. 2A, the renal artery 12, as with most arteries and arterioles, is lined with smooth muscle 34 that controls the diameter of the renal artery lumen 13. Smooth muscle, in general, is an involuntary non-striated muscle found within the media layer of large and small arteries and veins, as well as various organs. The glomeruli of the kidneys, for example, contain a smooth muscle-like cell called the mesangial cell. Smooth muscle is fundamentally different from skeletal muscle and cardiac muscle in terms of structure, function, excitation-contraction coupling, and mechanism of contraction.

Smooth muscle cells can be stimulated to contract or relax by the autonomic nervous system, but can also react on stimuli from neighboring cells and in response to hormones and blood borne electrolytes and agents (e.g., vasodilators or vasoconstrictors). Specialized smooth muscle cells within the afferent arteriole of the juxtaglomerular apparatus of kidney 10, for example, produces renin which activates the angiotension II system.

The renal nerves 14 innervate the smooth muscle 34 of the renal artery wall 15 and extend lengthwise in a generally axial or longitudinal manner along the renal artery wall 15. The smooth muscle 34 surrounds the renal artery circumferentially, and extends lengthwise in a direction generally transverse to the longitudinal orientation of the renal nerves 14, as is depicted in FIG. 2B.

The smooth muscle 34 of the renal artery 12 is under involuntary control of the autonomic nervous system. An increase in sympathetic activity, for example, tends to contract the smooth muscle 34, which reduces the diameter of the renal artery lumen 13 and decreases blood perfusion. A decrease in sympathetic activity tends to cause the smooth muscle 34 to relax, resulting in vessel dilation and an increase in the renal artery lumen diameter and blood perfusion. Conversely, increased parasympathetic activity tends to relax the smooth muscle 34, while decreased parasympathetic activity tends to cause smooth muscle contraction.

FIG. 3A shows a segment of a longitudinal cross-section through a renal artery, and illustrates various tissue layers of the wall 15 of the renal artery 12. The innermost layer of the renal artery 12 is the endothelium 30, which is the innermost layer of the intima 32 and is supported by an internal elastic membrane. The endothelium 30 is a single layer of cells that contacts the blood flowing through the vessel lumen 13. Endothelium cells are typically polygonal, oval, or fusiform, and have very distinct round or oval nuclei. Cells of the endothelium 30 are involved in several vascular functions, including control of blood pressure by way of vasoconstriction and vasodilation, blood clotting, and acting as a barrier layer between contents within the lumen 13 and surrounding tissue, such as the membrane of the intima 32 separating the intima 32 from the media 34, and the adventitia 36. The membrane or maceration of the intima 32 is a fine, transparent, colorless structure which is highly elastic, and commonly has a longitudinal corrugated pattern.

Adjacent the intima 32 is the media 33, which is the middle layer of the renal artery 12. The media is made up of smooth muscle 34 and elastic tissue. The media 33 can be readily

identified by its color and by the transverse arrangement of its fibers. More particularly, the media **33** consists principally of bundles of smooth muscle fibers **34** arranged in a thin plate-like manner or lamellae and disposed circularly around the arterial wall **15**. The outermost layer of the renal artery wall **15** is the adventitia **36**, which is made up of connective tissue. The adventitia **36** includes fibroblast cells **38** that play an important role in wound healing.

A perivascular region **37** is shown adjacent and peripheral to the adventitia **36** of the renal artery wall **15**. A renal nerve **14** is shown proximate the adventitia **36** and passing through a portion of the perivascular region **37**. The renal nerve **14** is shown extending substantially longitudinally along the outer wall **15** of the renal artery **12**. The main trunk of the renal nerves **14** generally lies in or on the adventitia **36** of the renal artery **12**, often passing through the perivascular region **37**, with certain branches coursing into the media **33** to enervate the renal artery smooth muscle **34**.

Embodiments of the disclosure may be implemented to provide varying degrees of denervation therapy to innervated renal vasculature. For example, embodiments of the disclosure may provide for control of the extent and relative permanency of renal nerve impulse transmission interruption achieved by denervation therapy delivered using a treatment apparatus of the disclosure. The extent and relative permanency of renal nerve injury may be tailored to achieve a desired reduction in sympathetic nerve activity (including a partial or complete block) and to achieve a desired degree of permanency (including temporary or irreversible injury).

Returning to FIGS. 3B and 3C, the portion of the renal nerve **14** shown in FIGS. 3B and 3C includes bundles **14a** of nerve fibers **14b** each comprising axons or dendrites that originate or terminate on cell bodies or neurons located in ganglia or on the spinal cord, or in the brain. Supporting tissue structures **14c** of the nerve **14** include the endoneurium (surrounding nerve axon fibers), perineurium (surrounds fiber groups to form a fascicle), and epineurium (binds fascicles into nerves), which serve to separate and support nerve fibers **14b** and bundles **14a**. In particular, the endoneurium, also referred to as the endoneurium tube or tubule, is a layer of delicate connective tissue that encloses the myelin sheath of a nerve fiber **14b** within a fasciculus.

Major components of a neuron include the soma, which is the central part of the neuron that includes the nucleus, cellular extensions called dendrites, and axons, which are cable-like projections that carry nerve signals. The axon terminal contains synapses, which are specialized structures where neurotransmitter chemicals are released in order to communicate with target tissues. The axons of many neurons of the peripheral nervous system are sheathed in myelin, which is formed by a type of glial cell known as Schwann cells. The myelinating Schwann cells are wrapped around the axon, leaving the axolemma relatively uncovered at regularly spaced nodes, called nodes of Ranvier. Myelination of axons enables an especially rapid mode of electrical impulse propagation called saltation.

In some embodiments, a treatment apparatus of the disclosure may be implemented to deliver denervation therapy that causes transient and reversible injury to renal nerve fibers **14b**. In other embodiments, a treatment apparatus of the disclosure may be implemented to deliver denervation therapy that causes more severe injury to renal nerve fibers **14b**, which may be reversible if the therapy is terminated in a timely manner. In preferred embodiments, a treatment apparatus of the disclosure may be implemented to deliver denervation therapy that causes severe and irreversible injury to renal nerve fibers **14b**, resulting in permanent cessation of renal

sympathetic nerve activity. For example, a treatment apparatus may be implemented to deliver a denervation therapy that disrupts nerve fiber morphology to a degree sufficient to physically separate the endoneurium tube of the nerve fiber **14b**, which can prevent regeneration and re-innervation processes.

By way of example, and in accordance with Seddon's classification as is known in the art, a treatment apparatus of the disclosure may be implemented to deliver a denervation therapy that interrupts conduction of nerve impulses along the renal nerve fibers **14b** by imparting damage to the renal nerve fibers **14b** consistent with neurapraxia. Neurapraxia describes nerve damage in which there is no disruption of the nerve fiber **14b** or its sheath. In this case, there is an interruption in conduction of the nerve impulse down the nerve fiber, with recovery taking place within hours to months without true regeneration, as Wallerian degeneration does not occur. Wallerian degeneration refers to a process in which the part of the axon separated from the neuron's cell nucleus degenerates. This process is also known as anterograde degeneration. Neurapraxia is the mildest form of nerve injury that may be imparted to renal nerve fibers **14b** by use of a treatment apparatus according to embodiments of the disclosure.

A treatment apparatus may be implemented to interrupt conduction of nerve impulses along the renal nerve fibers **14b** by imparting damage to the renal nerve fibers consistent with axonotmesis. Axonotmesis involves loss of the relative continuity of the axon of a nerve fiber and its covering of myelin, but preservation of the connective tissue framework of the nerve fiber. In this case, the encapsulating support tissue **14c** of the nerve fiber **14b** is preserved. Because axonal continuity is lost, Wallerian degeneration occurs. Recovery from axonotmesis occurs only through regeneration of the axons, a process requiring time on the order of several weeks or months. Electrically, the nerve fiber **14b** shows rapid and complete degeneration. Regeneration and re-innervation may occur as long as the endoneurial tubes are intact.

A treatment apparatus may be implemented to interrupt conduction of nerve impulses along the renal nerve fibers **14b** by imparting damage to the renal nerve fibers **14b** consistent with neurotmesis. Neurotmesis, according to Seddon's classification, is the most serious nerve injury in the scheme. In this type of injury, both the nerve fiber **14b** and the nerve sheath are disrupted. While partial recovery may occur, complete recovery is not possible. Neurotmesis involves loss of continuity of the axon and the encapsulating connective tissue **14c**, resulting in a complete loss of autonomic function, in the case of renal nerve fibers **14b**. If the nerve fiber **14b** has been completely divided, axonal regeneration causes a neuroma to form in the proximal stump.

A more stratified classification of neurotmesis nerve damage may be found by reference to the Sunderland System as is known in the art. The Sunderland System defines five degrees of nerve damage, the first two of which correspond closely with neurapraxia and axonotmesis of Seddon's classification. The latter three Sunderland System classifications describe different levels of neurotmesis nerve damage.

The first and second degrees of nerve injury in the Sunderland system are analogous to Seddon's neurapraxia and axonotmesis, respectively. Third degree nerve injury, according to the Sunderland System, involves disruption of the endoneurium, with the epineurium and perineurium remaining intact. Recovery may range from poor to complete depending on the degree of intrafascicular fibrosis. A fourth degree nerve injury involves interruption of all neural and supporting elements, with the epineurium remaining intact.

The nerve is usually enlarged. Fifth degree nerve injury involves complete transection of the nerve fiber **14b** with loss of continuity.

Turning now to FIG. 4, there is illustrated a treatment catheter comprising a jet and electrode arrangement configured to deliver a pressurized, electrically conductive fluid spray through a wall of a target vessel and ablate target tissue adjacent the target vessel wall in accordance with various embodiments. In FIG. 4, the treatment catheter **102** is shown deployed within a lumen of a patient's renal artery **12**. The treatment catheter **102**, according to various embodiments, includes a flexible shaft having a proximal end, a distal end, and a lumen arrangement extending between the proximal and distal ends. The length of the shaft is sufficient to access the patient's renal artery **12** relative to a percutaneous access location.

The lumen arrangement of the catheter **102** includes a pressurizable lumen **106** configured to receive a pressurized conductive fluid at its proximal end. The conductive fluid may be pressurized in the range of about 100 to 500 psi, for example. A nozzle **108** is fluidly coupled to the distal end of the pressurized bowl lumen **106**. The nozzle **108** is configured to direct a jet of pressurized conductive fluid at a wall **15** of the renal artery **12** to create or expand a hole through the artery wall **15**. The nozzle may have a diameter ranging from about 0.001 to 0.005 inch, for example.

In some configurations, the nozzle **108** may include a tissue-penetrating feature that facilitates dissection of the renal artery wall **15**. For example, a leading surface of the nozzle **108** may have a sharpened edge. In such embodiments, the nozzle **108** can be advanced through the hole in the artery wall **15** to a location at or extending beyond an outer surface of the artery wall **15**. Prior to advancing the nozzle **108** through the hole, a jet of pressurized conductive fluid can be used to expand the diameter of the hole, which serves to increase the ease by which the nozzle **108** can be advanced through the hole.

In other configurations, embodiments of which are described hereinbelow, an elongated member having a tissue-penetrating feature (e.g., needle) at its distal end can be displaced axially within the pressurizable lumen **106**. With the catheter's distal tip positioned adjacent the wall **15** of the renal artery **12**, the elongated member is advanced so that the tissue-penetrating feature penetrates into and through the renal artery wall **15**.

After piercing or expanding a previously created hole through the renal artery wall **15**, the conductive fluid is dispensed from the nozzle **108** to fill at least some perivascular space adjacent to the hole. In configurations where the nozzle **108** is not advanced through the hole, the conductive fluid dispensed from the nozzle **108** also fills the hole. At least one electrical conductor extends at least partially along the catheter **102** and terminates proximate or at the distal end of the pressurizer the lumen **106**. The electrical conductor is configured to conduct high-frequency AC energy (e.g., radiofrequency energy) to the conductive fluid sufficient to ablate perivascular renal nerve tissue **111** in contact with the conductive fluid.

The conductive fluid preferably has an impedance lower than that of the renal artery and perivascular tissue proximate the hole. In some embodiments, the conductive fluid is cooled to a temperature sufficient to provide cooling at the renal artery treatment site. In other embodiments, a cooling arrangement separate from the pressurized lumen **106** can be incorporated into the catheter **102** to provide cooling at the renal artery treatment site. For example, a separate infusion of

nonconductive fluid can be used for artery cooling and to decrease RF energy losses in the renal artery lumen.

In some embodiments, the nozzle **108** comprises electrically conductive material **109**, such as a metallic annular tapered ring, which defines an electrode. An electrical conductor is coupled to the electrically conductive nozzle **108** and extends along the length of the catheter **102** to its proximal end. In other configurations, the electrical conductor (e.g., a wire or conductive composite elongated member) extends between the distal and proximal ends of the catheter **102**, and the distal tip of the electrical conductor defines the electrode **109**. For example, the pressurizable lumen **106** can include a metallic tube that serves as an electrical conductor between a proximal energy source and the distal tip of the metallic tube which serves as an electrode **109**. In other configurations, at least a proximal portion of the pressurizable lumen **106** comprises nonconductive material, and the nozzle **108** comprises an electrically conductive element **109**. In further configurations, an electrical conductor extends between the distal and proximal ends of the catheter **102** for electrically coupling the nozzle **108** with an external energy source at the proximal end of the catheter **102**.

The distal end of one or both of the catheter **102** and pressurizable lumen **106** may incorporate a pre-formed curve that facilitates proper positioning of the nozzle **108** against the wall **15** of the renal artery. For example, the distal ends of the catheter **102** and pressurizable lumen **106** may incorporate pre-formed curves that together can form a complex curved shape which can position the nozzle **108** at or near perpendicular with respect to the renal artery wall **15**. In other configurations, the pressurizable lumen **106** can be fashioned as a metallic tube, and at least the distal end of the pressurizable lumen **106** can include a shape-memory tube section. When extended beyond the distal tip of the catheter **102**, the shape-memory tube section assumes a predetermined curved shape for orienting the nozzle at a desired angle (e.g., 90°+/20°) relative to the renal artery wall **15**. In further configurations, a tensioning wire or cable can be connected at the distal tip of the catheter **102**. Desired curvature of the distal end or tip of the catheter **102** can be achieved by applying an appropriate force to the tensioning wire/cable, allowing the clinician to orient the nozzle **108** at a desired angle relative to the renal artery wall **15**.

In some embodiments, the treatment catheter **102** includes a single pressurizable lumen **106** fluidly coupled to a multiplicity of the nozzles **108**. The multiplicity of nozzles **108** may be fluidly coupled to the single pressurizable lumen **106** via an intervening structure, such as a manifold, balloon, chamber or a series of orifices in a tube, for example. The intervening structure is preferably configured to channel pressurized conductive fluid from the single pressurizable lumen **106** to a multiplicity of the nozzles **108**.

FIG. 5 illustrates a treatment catheter comprising a multiplicity of jet and electrode arrangements each configured to deliver a pressurized, electrically conductive fluid spray through a wall of a target vessel and ablate target tissue adjacent the target vessel wall in accordance with various embodiments. In the embodiment illustrated in FIG. 5, a treatment catheter **102** includes multiple jets that can be used to concurrently or serially ablate separate locations along and around the renal artery perivascular tissue. An expandable stabilization arrangement can be provided to position the jet nozzles against the renal artery wall and stabilize the position of the nozzles during the ablation procedure.

The embodiment of FIG. 5 shows a treatment catheter **102** that employs a multiplicity of jet arrangements. The catheter **102** includes a multiplicity of pressurizable lumens **106a** and

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106*b* fluidly coupled to a multiplicity of nozzles 208*a* and 208*b*, respectively. The treatment catheter 102 further includes an expandable balloon or mesh structure 221 provided at a distal end of the catheter 102. The expandable structure 221 is configured to position the nozzles 208*a* and 208*b* against the wall 15 of the renal artery 12 and stabilize the position of the nozzles 208*a* and 208*b* during the ablation procedure. FIG. 5 further shows extension lumens 204*A* and 204*B* fluidly coupled to pressurizable lumens 106*a* and 106*b*, respectively.

In some configurations, the extension lumens 204*A* and 204*B* define end sections of the pressurizable lumens 106*a* and 106*b* that terminate on an exterior surface of the expandable structure 221. In other embodiments, the extension lumens 204*A* and 204*B* define lumen structures integral to the expandable structure 221, which are fluidly coupled to pressurizable lumens 106*a* and 106*b* during catheter fabrication. For example, the extension lumens 204*A* and 204*B* may be formed into the surface of an expandable balloon structure 221. By way of further example, the extension lumens 204*A* and 204*B* may be polymeric or metallic tubes having distal ends that terminate at the surface of an expandable mesh structure 221.

According to some embodiments, the distal ends of the extension lumens 204*A* and 204*B* include an electrically conductive material, and this conductive material is electrically coupled to an electrical conductor that runs along the length of the catheter 102. For example, the extension lumens 204*a* and 204*B* define end sections of metallic tubes 106*A* and 106*B*, respectively. In other embodiments, the pressurizable lumens 106*a* and 106*b* can be formed from polymeric material and the distal ends of the extension lumens 204*a* and 204*B* can include electrically conductive material which is electrically coupled to an electrical conductor that runs along the length of the catheter 102. After delivering the conductive fluid into the perivascular space 111, radiofrequency energy is communicated to the electrically conductive material at the distal ends of the extension lumens 204*a* and 204*B*. The conductive fluid provides a low impedance pathway to the perivascular renal nerve tissue contained within the perivascular space 111 for the RF energy.

The jet arrangements shown in the illustrative embodiment of FIG. 5 is useful for ablating perivascular renal nerve tissue at two separate locations within the renal artery 15. In FIG. 5, the two extension lumens 204*a* and 204*b* are spaced apart from one another both circumferentially and axially. As such, two circumferentially and axially spaced regions of perivascular renal nerve tissue proximate the expandable structure 221 can be ablated. It is noted that the axial spacing between the extension lumens 204*a* and 204*b* can be eliminated for treatment catheters implemented to ablate a circumferential region of perivascular renal nerve tissue.

Additional jet arrangements can be incorporated into the treatment catheter 102. For example, the expandable structure 221 and lumen arrangement of the catheter 102 can be configured to accommodate four jet arrangements spaced apart from one another both axially and circumferentially, so that each jet and associated electrode element can ablate approximately one-fourth of a circumferential region of the perivascular renal nerve tissue. By way of further example, the expandable structure 221 and lumen arrangement of the catheter 102 can be configured to accommodate six jet arrangements spaced apart from one another both axially and circumferentially, such that each jet and associated electrode element can ablate approximately one-sixth of a circumferential region of the perivascular renal nerve tissue. Ablation of perivascular renal nerve tissue adjacent each of the jet and

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electrode element arrangement using the RF energy can be performed serially or sequentially.

It is understood that a treatment catheter 102 which incorporates a multiplicity of jet arrangements can include an expandable structure 221 configured to position the multiplicity of jet arrangements in one or both of axially and circumferentially spaced relationships to one another. Also, each of the jet arrangements can be fluidly coupled to an individual pressurizable lumens of the treatment catheter 102, or some or all of the jet arrangements can be fluidly coupled to a common pressurizable lumen. Ablation of perivascular renal nerve tissue using the jet and electrode element arrangements can be performed serially or sequentially, irrespective of whether the jet arrangements are fluidly coupled to separate lumens or a common lumen.

Although not shown in FIG. 5 for purposes of simplicity, expandable structure 221 includes an activation feature (e.g., pressurizable lumen(s) or push/pull wire(s)) for transforming the expandable structure 221 between low-profile introduction and deployment configurations. It is noted that an expandable balloon structure 221 can be implemented to include a cooling arrangement in the form of a recirculating cooling circuit or a phase-change cooling arrangement.

According to various method embodiments, the distal end of the treatment catheter 102 is delivered to a patient's renal artery 12 using one or both of a guiding catheter and a delivery sheath. During the delivery procedure, the expandable structure 221 is in its collapsed low-profile introduction configuration. After the expandable structure 221 is positioned at a desired location within the renal artery 12, the expandable structure 221 is activated, which centers the catheter 102 within the renal artery 12 and positions the nozzles 208*a* and 208*b* against the wall 15 of the renal artery 12. The jets are activated for a brief duration of time and at an appropriate pressure to create a hole through the renal artery wall 15 using high-pressure electrically conductive fluid. The conductive fluid fills the holes in the artery wall 15 and perivascular space 111 adjacent the holes. Radiofrequency energy is delivered to the perivascular renal nerve tissue included in the perivascular space 111 via the nozzles 208*a* and 208*b* or electrically conductive electrode elements at or near the nozzles 208*a* and 208*b*.

In accordance with various embodiments, and with reference to FIGS. 6A-6C, a catheter apparatus 200 can be configured to accommodate a conductive wire which can be used to create a hole through the renal artery wall 15. A low-pressure conductive fluid jet can be used to expand the hole in the artery wall 15 created by the conductive wire and, if needed, to dissect the perivascular space 111. RF energy can be transferred to the conductive fluid at the distal tip of the conductive wire to ablate the perivascular renal nerve tissue.

FIGS. 6A-6C illustrate various features of a catheter apparatus 200 at different stages of an ablation procedure in accordance with embodiments of the disclosure. As shown in FIG. 6A, the catheter apparatus 200 includes a treatment catheter 202 having a pressurizable lumen 207 dimensioned to receive an elongated member 212. The elongated member 212 is displaceable within the pressurizable lumen 207 and extendable beyond a distal opening 208 which defines a nozzle of the pressurizable lumen 207. The shape of the nozzle 208 in FIGS. 6A-6C is not shown for purposes of simplicity. The elongated member 212 is insulated along its length except at a distal end section 204, which remains exposed. The exposed distal end section 204 includes a tissue-penetrating feature 206. The tissue-penetrating feature 206 can be used to create a pilot hole 82 in the wall 15 of a patient's renal artery, which is best seen in FIG. 6B.

According to other embodiments, and with continued reference to FIG. 6B, the elongated member **212** includes a distal short conductive wire **204** having a tissue-penetrating feature **206** at its distal end. In the embodiment shown in FIG. 6B, the distal short conductive wire **204** is connected to a proximal nonconductive (e.g., plastic) section of the elongated member **212**. The pressurizable lumen **207**, according to this embodiment, comprises a conductive metal tube. An electrical conductor **215** has opposing ends respectively connected to a distal location of the conductive metal tube **207** and a proximal location of the short conductive wire **204**. The length of the electrical conductor **215** provides slack to allow for free axial movement of the short conductive wire **204** between retracted and extended positions. In an alternative embodiment, the pressurizable lumen **207** can be formed from non-conductive material, and an electrical conductor can extend between a proximal end of the pressurizable lumen **207** and a proximal end of the short conductive wire **204**. The short conductive wire **204** in FIG. 6B is shown penetrating through the wall **15** of the patient's renal artery.

In the embodiment shown in FIG. 6C, the elongated member **212** comprises a conductive wire which includes a tissue-penetrating feature **206** at its distal end. Depending on the diameter of the distal end of the elongated member **212**, a relatively low-pressure jet of conductive fluid can be directed into the pilot hole **82** for purposes of expanding the size of the pilot hole **82** and dissecting the perivascular space adjacent the pilot hole **82**. FIG. 6C illustrates retraction of the elongated member **212** into the pressurizable lumen **207**, and dispensing of a conductive fluid into the pilot hole **82** and into perivascular space which includes perivascular renal nerve tissue **86**. After dispensing a sufficient volume of conductive fluid into the perivascular space, the distal end of the elongated member **212** is advanced into the pilot hole **82** so that the RF energy can be transmitted from the distal end of the elongated member **212** to the conductive fluid in contact with the perivascular renal nerve tissue **86**. The above-described ablation procedure illustrated in FIGS. 6A-6C can be performed for each jet and electrode arrangement incorporated in a catheter arrangement **200** in accordance with various embodiments of the disclosure.

FIG. 7 shows a representative RF renal therapy apparatus **100** in accordance with various embodiments of the disclosure. The apparatus **100** illustrated in FIG. 7 includes an external control unit **110** which includes an RF generator **120**. The external control unit **110** typically includes some or all of power control circuitry, timing control circuitry, temperature measuring circuitry, and impedance measuring circuitry. An ablation catheter **102** of the RF renal therapy apparatus **100** includes a shaft **104** having a pressurizable lumen **106** which terminates with a nozzle **108**. The nozzle **108** or an electrically conductive element **109** is configured to function as an electrode and coupled to a separate conductor **107** or the pressurizable lumen **106** if fashioned as a metallic tube. The distal end of the pressurizable lumen **106** and the nozzle are preferably held at a desired orientation within the patient's renal artery during ablation by a stabilization arrangement (not shown) of a type previously described.

The external control unit **110** includes a pump **112** which is fluidly coupled to a reservoir **115** containing electrically conductive fluid. The external control unit **110** controls the amount of pressure generated by the pump **112**. For example, the external control unit **110** can control the pump **112** to dispense conductive fluid at a relatively high pressure for creating a hole through an artery wall and dissecting target tissue adjacent the artery wall. The external control unit **110** may control the pump **112** for dispensing conductive fluid at

a relatively low pressure for expanding a pilot hole created by a piercing needle or other tissue-penetrating appliance.

The RF generator **120** preferably includes a pad electrode **124** which is configured to comfortably engage the patient's back or other portion of the body near the kidneys. The RF generator **120**, nozzle or separate electrode **108**, and pad electrode **124** preferably operate in a unipolar ablation mode. Radiofrequency energy produced by the RF generator **120** is coupled to the nozzle **108** or conductive element **109** via the conductor **107** or pressurizable lumen **106** if metallic, propagates through the conductive fluid, and ablates target tissue, such as perivascular renal nerve tissue, in accordance with a predetermined activation sequence.

As is further shown in FIG. 7, a cooling fluid can be delivered to the ablation site within the renal artery under the control of a cooling control unit **152**. The cooling control unit **152** includes a pump **154** and is fluidly coupled to a reservoir **156** containing a nonconductive (or conductive) cooling fluid or cryogen. As discussed previously, the cooling control unit **152** can dispense a biocompatible liquid coolant **164** to the ablation site or a liquid thermal transfer agent within a closed circulation or phase-change cooling circuit.

In general, when renal artery tissue temperatures rise above about 113° F. (50° C.), protein is permanently damaged (including those of renal nerve fibers). If heated over about 65° C., collagen denatures and tissue shrinks. If heated over about 65° C. and up to 100° C., cell walls break and oil separates from water. Above about 100° C., tissue desiccates.

According to some embodiments, the RF generator **120** is configured to control activation and deactivation of the nozzle **108**/conductive element **109** in accordance with a predetermined energy delivery protocol and in response to signals received from temperature measuring circuitry. The RF generator **120** controls radiofrequency energy delivered to the nozzle **108**/conductive element **109** so as to maintain the current densities at a level sufficient to cause heating of the perivascular renal tissue to at least a temperature of 55° C., for example.

Temperature sensors can be situated at the nozzle **108**/conductive element **109** to provide continuous monitoring of renal artery tissue temperatures, and RF generator power can be automatically adjusted so that target temperatures are achieved and maintained. An impedance sensor arrangement may be used to measure and monitor electrical impedance during RF denervation therapy, and the power and timing of the RF generator **120** may be moderated based on the impedance measurements or a combination of impedance and temperature measurements. Marker bands **314** can be placed on one or multiple parts of the nozzle/nozzle region and/or shaft **104** to enable visualization during the procedure. A guidewire or guiding catheter can be used to locate the renal artery to be treated, and the catheter **102** can be advanced over the guidewire/guiding catheter and through the ostium of the renal artery.

The embodiments shown in the figures have been generally described in the context of intravascular-based ablation of perivascular renal nerves for control of hypertension. It is understood, however, that embodiments of the disclosure have applicability in other contexts, such as energy delivery from within other vessels of the body, including other arteries, veins, and vasculature (e.g., cardiac and urinary vasculature and vessels), and other tissues of the body, including various organs. For example, the treatment catheter **102** can be configured for deployment within the renal vein, and the pressurizable lumen **106** and electrode **109** can be advanced through a hole created in the renal artery wall. The pressurizable lumen **106** and electrode **109** can be further advanced to a

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location proximate perivascular renal nerve tissue surrounding the adjacent the near wall of the renal artery. A steering or tensioning wire and/or a pre-formed curve can be provided at the distal tip of the pressurizable lumen **106** to allow the clinician to access perivascular renal nerve tissue adjacent the far wall of the renal artery. Conductive fluid can be dispensed through the perivascular space surrounding the adjacent renal artery and within the perivascular renal nerve tissue included within the perivascular space. RF ablation can be conducted in step-wise fashion at discrete locations about the periphery of the renal artery or in a single delivery of RF energy (assuming conductive fluid nearly or entirely surrounds the renal artery).

By way of further example, an appropriately sized pressurizable lumen **106** and electrode **109** can be deployed in a cardiac chamber, such as the right atrium for treating reentrant tachyarrhythmias, or a cardiac vessel, such as the ostium of the pulmonary vein for treating atrial fibrillation. Various embodiments may be configured for deployment in the urethra to treat benign prostatic hyperplasia (BPH) or to treat a tumor using an appropriately sized pressurizable lumen **106** and electrode **109** of a type described hereinabove.

It is to be understood that even though numerous characteristics of various embodiments have been set forth in the foregoing description, together with details of the structure and function of various embodiments, this detailed description is illustrative only, and changes may be made in detail, especially in matters of structure and arrangements of parts illustrated by the various embodiments to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed.

What is claimed is:

1. An apparatus, comprising:

a catheter comprising a flexible shaft having a proximal end, a distal end, a length, and a lumen arrangement extending between the proximal and distal ends, the length of the shaft sufficient to access a patient's renal artery relative to a percutaneous access location;

a pressurizable lumen of the lumen arrangement configured to receive a pressurized conductive fluid;

a nozzle fluidly coupled to a distal end of the pressurizable lumen, the nozzle configured to direct a jet of the pressurized conductive fluid at a wall of the renal artery to create or expand a hole through the artery wall and to fill the hole and at least some of perivascular space adjacent to the hole with the conductive fluid; and

at least one electrical conductor extending at least partially along the shaft and terminating proximate or at the distal end of the pressurizable lumen, the at least one electrical conductor configured to conduct radio frequency energy to the conductive fluid sufficient to ablate perivascular renal nerve tissue in contact with the conductive fluid;

wherein the pressurizable lumen comprises electrically conductive material that extends between the distal and proximal ends of the shaft.

2. The apparatus of claim 1, wherein the conductive fluid has an impedance lower than that of renal artery tissue proximate the hole.

3. The apparatus of claim 1, wherein at least the nozzle comprises electrically conductive material.

4. The apparatus of claim 1, wherein at least a proximal portion of the pressurizable lumen comprises non-conductive material, the nozzle comprises an electrically conductive element.

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5. The apparatus of claim 1, comprising:

a conductive wire covered with an electrically insulating material and having an exposed tip portion, the tip portion configured to create a pilot hole through the artery wall;

wherein a relatively low pressure conductive fluid jet is configured to expand the pilot hole in the artery wall and dissect the perivascular space, and the radiofrequency energy is transferred to the conductive fluid via the tip of the conductive wire.

6. The apparatus of claim 1, comprising a plurality of the pressurizable lumens fluidly coupled to a plurality of the nozzles, each of the pressurizable lumens individually pressurizable.

7. The apparatus of claim 1, comprising a plurality of the pressurizable lumens fluidly coupled to a plurality of the nozzles, at least some of the pressurizable lumens fluidly coupled to a common pressurizable lumen and commonly pressurizable.

8. The apparatus of claim 1, comprising:

a plurality of the pressurizable lumens fluidly coupled to a plurality of the nozzles; and

an expandable balloon or mesh provided at the distal end of the shaft and configured to position the nozzles against the artery wall and stabilize the position of the nozzles during ablation.

9. The apparatus of claim 1, comprising:

a plurality of the pressurizable lumens fluidly coupled to a plurality of the nozzles;

an expandable balloon or mesh provided at the distal end of the shaft and configured to position the nozzles against the artery wall and stabilize the position of the nozzles during ablation; and

an external control unit fluidly coupled to the pressurizable lumens and configured to control the jets of the pressurized conductive fluid at the wall of the renal artery to concurrently ablate separate locations along and around the renal artery perivascular tissue.

10. The apparatus of claim 1, comprising:

a plurality of the pressurizable lumens fluidly coupled to a plurality of the nozzles;

an expandable balloon or mesh provided at the distal end of the shaft and configured to position the nozzles against the artery wall and stabilize the position of the nozzles during ablation; and

an external control unit fluidly coupled to the pressurizable lumens and configured to control the jets of the pressurized conductive fluid at the wall of the renal artery to serially or sequentially ablate separate locations along and around the renal artery perivascular tissue.

11. The apparatus of claim 1, wherein the conductive fluid is cooled to a temperature sufficient to provide cooling at a renal artery ablation site.

12. The apparatus of claim 1, comprising a cooling arrangement separate from the pressurizable lumen and configured to provide cooling at a renal artery treatment site.

13. An apparatus, comprising:

a catheter dimensioned for advancement through a vessel of the body;

a pressurizable lumen of the catheter configured to receive a pressurized conductive fluid;

a nozzle fluidly coupled to a distal end of the pressurizable lumen, the nozzle configured to direct a jet of the pressurized conductive fluid at a wall of a target vessel to create or expand a hole through the target vessel and to fill the hole and at least some of the space adjacent to the hole with the conductive fluid; and

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at least one electrical conductor extending at least partially along the catheter and terminating proximate or at the distal end of the pressurizable lumen, the at least one electrical conductor configured to conduct radio frequency energy to the conductive fluid sufficient to ablate target tissue in contact with the conductive fluid; wherein the pressurizable lumen comprises electrically conductive material that extends between the distal and proximal ends of the shaft.

14. The apparatus of claim **13**, wherein at least a proximal portion of the pressurizable lumen comprises non-conductive material, the nozzle comprises electrically conductive material.

15. The apparatus of claim **13**, comprising:

a conductive wire covered with an electrically insulating material and having an exposed tip portion, the tip portion configured to create a pilot hole through the target vessel;

wherein a relatively low pressure conductive fluid jet is configured to expand the pilot hole in the target vessel wall, and the radiofrequency energy is transferred to the conductive fluid via the tip of the conductive wire.

16. A method, comprising:

advancing a catheter through a renal artery of the body to a target location proximate target tissue adjacent an outer wall of the renal artery, wherein the target tissue comprises perivascular renal nerve tissue;

creating a hole through the outer wall of the renal artery at the target location;

filling the hole and at least some of the space adjacent to the hole with conductive fluid via a lumen of the catheter; and

conducting radiofrequency energy along the catheter and to the conductive fluid filling the hole and the at least some of the space adjacent to the hole sufficient to ablate the target tissue.

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17. The method of claim **16**, comprising:

creating a plurality of the holes through the renal artery at a plurality of one or both of circumferentially and axially spaced-apart target locations;

filling the holes and at least some of the space adjacent to the holes with the conductive fluid; and

conducting radiofrequency energy along the catheter and to the conductive fluid filling the holes and the at least some of the space adjacent to the holes sufficient to ablate the target tissue.

18. The method of claim **16**, further comprising:

prior to filling the hole, expanding the hole and dissecting perivascular space adjacent the hole using a low-pressure jet of conductive fluid.

19. The method of claim **16**, wherein the catheter comprises:

a flexible shaft having a proximal end, a distal end, a length, the length of the shaft sufficient to access the renal artery relative to a percutaneous access location;

a nozzle fluidly coupled to a distal end of the lumen, the nozzle being configured to direct a jet of the conductive fluid at the outer wall of the renal artery to create the hole through the outer wall and to fill the hole and at least some of the space adjacent to the hole with the conductive fluid; and

at least one electrical conductor extending at least partially along the shaft and terminating proximate or at the distal end of the lumen, the at least one electrical conductor configured to conduct radiofrequency energy to the conductive fluid sufficient to ablate perivascular renal nerve tissue in contact with the conductive fluid;

wherein the lumen comprises electrically conductive material that extends between the distal and proximal ends of the shaft.

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